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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/591,834	03/15/2007	Masanobu Akimoto	31671-235624	3085

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EXAMINER	
GRUN, JAMES LESLIE	
ART UNIT	PAPER NUMBER
1641	
MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/591,834	AKIMOTO ET AL.	
	Examiner	Art Unit	
	JAMES L. GRUN	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 September 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2,4,5,7,9-11,13 and 103-112* is/are pending in the application.

4a) Of the above claim(s) *2,4,5,7,9-11,13 and 106-111* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *103-105 and 112* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

The amendment filed 16 September 2009 is acknowledged and has been entered. Claim 112 is newly added. Claims 2, 4, 5, 7, 9-11, 13, and 103-112 remain in the case. Claims 2, 4, 5, 7, 9-11, 13, and 106-111 have been withdrawn from further consideration as being drawn to a non-elected invention.

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The specification is objected to under 35 U.S.C. § 112, first paragraph, as failing to provide an adequate written description of the invention, and failing to adequately teach how to make and/or use the invention, i.e. failing to provide an enabling disclosure.

The specification is objected to and claims 105 and 112 are rejected under 35 U.S.C. § 112, first paragraph, as failing to provide an adequate written description of the invention and failing to provide an enabling disclosure, because the specification does not provide evidence that the claimed biological materials are: (1) known and readily available to the public; (2) reproducible from the written description; or, (3) deposited in compliance with the criteria set forth in 37 CFR §§ 1.801-1.809.

It is unclear if cell lines which produce antibodies having the exact chemical identity and properties of the antibodies designated PDOA1 and PDOA2, produced by hybridoma cell lines deposited as FERM BP-10275 and FERM BP-10276, respectively, are known and publicly available, or can be reproducibly isolated without undue experimentation. Accordingly, filing of

evidence of the reproducible production of the cell lines and antibodies necessary to practice the instant invention or filing of evidence of deposit is required. Without a publicly available deposit of the above cell lines, one of skill in the art could not be assured of the ability to practice the invention as claimed. Exact replication of: the claimed cell line; the cell lines which produce the chemically and functionally distinct antibodies claimed; and/or, the claimed antibody's amino acid or nucleic acid sequence is an unpredictable event. For example, very different V_H chains can combine with the same V_L chain to produce antibody binding sites with nearly the same size, shape, antigen specificity, and affinity. A similar phenomenon can also occur when different V_H sequences combine with different V_L sequences to produce antibodies with very similar properties. These observations indicate that divergent variable region sequences, both in and out of complementarity-determining regions, can be folded to form similar binding site contours, which result in similar immunochemical characteristics. Therefore, it would require undue experimentation to reproduce the claimed monoclonal antibody species chemically as produced by the hybridomas designated PDOA1 and PDOA2, deposited as FERM BP-10275 and FERM BP-10276, respectively. A suitable deposit of the hybridomas would satisfy the enablement requirements of 35 U.S.C. § 112, first paragraph. See the criteria set forth in 37 CFR §§ 1.801-1.809.

If the deposits are made under the terms of the Budapest Treaty, then an affidavit or declaration by Applicant, or a statement by an attorney of record over his or her signature and registration number, stating that the specific biological materials have been deposited under the Budapest Treaty, that the biological materials will be irrevocably and without restriction or condition released to the public upon the issuance of a patent and that the biological materials will be replaced should they ever become non-viable, would satisfy the deposit requirement made herein.

If the deposits have not been made under the Budapest Treaty, then in order to certify that the deposits meet the criteria set forth in 37 CFR §§ 1.801-1.809, applicant may provide

assurance of compliance by an affidavit or declaration, or by a statement by an attorney of record over his or her signature and registration number, showing that:

(a) during the pendency of this application, access to the invention will be afforded to the Commissioner upon request;
(b) all restrictions upon availability to the public will be irrevocably removed upon granting of the patent;
(c) the deposits will be maintained in a public depository for a period of 30 years or 5 years after the last request or for the effective life of the patent, whichever is longer;
(d) the deposits were viable at the time of deposit; and,
(e) the deposits will be replaced if they should ever become non-viable.

Claims 103-105 and 112 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, and which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Applicant describes and desires a sandwich method wherein native and denatured ovalbumin allergens are detected simultaneously by using a combination of antibodies for immobilization and labeling of the allergens in a sample (see e.g., pages 18-19, 62-67). Applicant teaches the simultaneous detection as improved over the use of individual assays. Although one of skill in the art might realize from reading the disclosure that individual assays are useable in the invention, such possibility of use does not provide explicit or implicit indication to one of skill in the art that such were originally contemplated as part of applicant's invention since applicant specifically teaches against the use of individual assays and such possibility of use does not satisfy the written description requirements of 35 U.S.C. § 112, first

paragraph. Note that a description which renders obvious a claimed invention is not sufficient to satisfy the written description requirement. Applicant is requested to direct the Examiner's attention to specific passages where support for these newly recited limitations can be found in the specification as filed or is required to delete the new matter.

Further, claims lacking the simultaneous detection of native and denatured ovalbumin allergens, critical or essential to the practice of the invention described by applicant, are not enabled by the disclosure. See *In re Mayhew*, 527 F.2d 1229, 188 USPQ 356 (CCPA 1976).

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 103-105 and 112 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 103 is incomplete because of the omission of essential steps, such omission amounting to a gap between the steps; for example, there is no nexus between the analyzing step and any of the other steps. It is also not clear what is being detected if allergen is known to be trapped in the first step. Moreover, "the labeled second . . . antibody" lacks sufficient antecedent basis because no label is previously recited.

Claim 104 recites the limitation "the fixed second . . . antibody" in the last lines of the claim. There is insufficient antecedent basis for this limitation in the claim because no fixation is

previously recited. It is also not clear what is being detected if allergen is known to be prepared as a complex in the first step.

Further in claims 105 and 112, the deposit numbers should be clearly made part of the claim because it is not clear that the current parenthetical recitations of the deposit accession numbers are intended as a limitation, as they should be, or are merely exemplary of hybridomas producing the antibodies.

Applicant's arguments filed 16 September 2009 have been fully considered but they are not deemed to be persuasive.

Notwithstanding applicant's assertions to the contrary, applicant's amendments have not obviated rejections under this statute for the reasons set forth above.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
> (c) Subject matter developed by another person, which qualifies as prior art only under one or more subsections (e), (f) and (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.
>
> This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. § 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. § 102(f) or (g) prior art under 35 U.S.C. § 103.

Claims 103 and 105 are rejected under 35 U.S.C. § 103(a) as being unpatentable over the combined teachings of Narita et al. (JP 2002-253230), in view of the JPO machine translation, Kilshaw et al. (Clin. Exp. Immunol. 66: 481, 1986), and Mine et al. (J. Agric. Food Chem. 50: 2679, 2002).

Narita et al., in view of the JPO machine translation, generated and used monoclonal antibodies specific for native ovomucoid, heat denatured ovomucoid, and/or for both in immunoassays for detection of a common egg food allergen (see e.g.: claims; description ¶¶ [0006], [0026] - [0030]). The reference teaches that ovalbumin and ovotransferrin are also egg allergens (see e.g.: description ¶¶ [0002], [0026] - [0030]), but does not teach antibodies for their detection.

Kilshaw et al. generated and used monoclonal antibodies specific for native ovalbumin and ovalbumin denatured by treatment with urea, reducing agent, and carboxymethylation in immunoassays for detection of the food allergen.

Mine et al. teach the antigenicity and allergenicity of native and denatured egg white proteins. The reference teaches that antibody binding to reduced carboxymethylated or heated denatured ovalbumin was not significantly different (see Table 2).

It would have been obvious to one of ordinary skill in the art at the time the instant invention was made to have applied the methods of Narita et al. for the detection of an egg allergen to the detection of other egg allergens because the reference teaches the importance of detecting allergens in foods during processing and one of ordinary skill in the art would have had an extremely reasonable expectation of success in alternatively detecting ovalbumin as an allergen in food during processing in view of the availability of paired monoclonal antibodies

specific for two different epitopes in either native or denatured ovalbumin as taught in Kilshaw et al. One would have reasonably expected that antibodies specific for reduced carboxymethylated denatured ovalbumin would bind to heat denatured ovalbumin in view of the teachings of Mine et al. regarding the similar binding of both human and rabbit antibodies to ovalbumin alternatively denatured.

Thus, the claimed invention as a whole was clearly prima facie obvious, especially in the absence of evidence to the contrary.

Claims 104 and 112 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Narita et al. (JP 2002-253230), in view of the JPO machine translation, Kilshaw et al. (Clin. Exp. Immunol. 66: 481, 1986), and Mine et al. (J. Agric. Food Chem. 50: 2679, 2002) as applied to claims 103 and 105 above, and further in view of May et al. (US 5,602,040) and Yeung et al. (US 2003/0044869).

May et al. (US 5,602,040) teach a variety of embodiments of an analytical test device, which are now well known and conventional. Such test strip devices are for use in, for example, sandwich or competition immunoassays (cols. 2-3 and 8-9) for detection of analytes. With the choice of appropriate specific binding reagents, the general applicability of the test strip device is taught (e.g., col. 9). May et al. teach the use of direct labels such as minute colored particles, such as dye sols, metallic sols (e.g. gold) and colored latex particles (col. 5).

Yeung et al. (US 2003/0044869) teach test strips for the detection of food allergens such as egg allergens.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device taught by May et al. in order to detect food allergens as taught by the combined teachings of Narita et al., Kilshaw et al., and Mine et al. because May et al. teach that their device provides the advantage of a device that is suitable for use remotely and can give a result that is rapid and requires a minimum degree of skill and involvement from the user. One would have had a reasonable expectation of success in modifying the device of May et al. to detect the food allergens taught by Narita et al., Kilshaw et al., and Mine et al. because May et al. teach that the same assay device and principle can be used to determine a wide variety of analytes by choice of appropriate specific binding reagents and Yeung et al. specifically suggest test strip devices for performance of food allergen detection assays.

Thus, the claimed invention as a whole was clearly prima facie obvious, especially in the absence of evidence to the contrary.

Applicant's arguments filed 16 September 2009 with respect to the prior claims have been fully considered but are moot in view of the new ground(s) of rejection set forth herein above.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Morimatsu et al. (JP 2003-155297; WO 03/022876; EP 1 440 978) teach polyclonal antibodies to undenatured and/or denatured food allergens and the use thereof for detection of the allergens.

Campbell teaches the general procedure for the production of monoclonal antibodies (pages 3-6) and that substituting a monoclonal antibody for a polyclonal antibody in an established immunoassay "is not novel and is obvious" (page 45).

David et al. (US 4,376,110) teach sandwich immunoassays with monoclonal immunocapture and detection reagents which preferably bind to different epitopes on the same antigen (particularly col. 4, lines 19-33). The reference teaches that sandwich immunoassays may be performed in either "forward" or "reverse" sequential formats or in simultaneous formats (col. 1, line 47, through col. 2, line 46), and teaches the advantages of monoclonal antibodies particularly for simultaneous and reverse immunoassay formats (e.g. col. 3-4). Sandwich immunoassays with monoclonal antibodies were more sensitive and, in some method formats, reached equilibrium more rapidly than corresponding assays with polyclonal antibodies (col. 8, lines 11-38). However, David et al do not teach anti-ovalbumin antibodies.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James L. Grun, Ph.D., whose telephone number is (571) 272-0821. The examiner can normally be reached on weekdays from 11 a.m. to 7 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark Shibuya, SPE, can be contacted at (571) 272-0806.

The phone number for official facsimile transmitted communications to TC 1600, Group 1640, is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application, or requests to supply missing elements from Office communications, should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/J. L. G./
James L. Grun, Ph.D.
Examiner, Art Unit 1641
December 7, 2009

/Shafiqul Haq/
Primary Examiner, Art Unit 1641